

REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated October 24, 2008.

Applicants acknowledge and thank the Examiner for her time and consideration in telephone discussion on January 28, 2009 in which the outstanding rejections were discussed. In particular, the nature of bacteriophage enzymes and their characteristics and specificity were discussed. The claims and cited art were discussed, including the breadth of the claims and possible claim amendments.

Status of the Claims

Claims 1-24 are pending in the application. Claims 1-14, 18, and 24, which are withdrawn from consideration, have been canceled without prejudice. Claims 20 and 21 have been canceled without prejudice. Claims 15, 16, 19 and 22 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' specification and/or in the previously pending claims. In particular, Applicants point to the specification, including at paragraphs [0004], [0005], and [0009], pages 2-3, for the term "pneumococcal" in claim 15. Support for the language "obtained from bacteriophage" in claims 15 and 19 is found in the specification, for example at paragraph [0051], page 14. The phrase "wherein the combination of the at least two enzymes shows more than additive killing on a logarithmic scale" of claims 15 and 19 is supported in the specification, for example at paragraph [0032], page 10. No new matter has been added by way of these amendments. Thus, as a result of the foregoing amendment, claims 15-17, 19, 22 and 23 are under consideration. Reconsideration of this application and allowance of the claims is respectfully requested.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Rejections – 35 USC § 112

The Examiner has rejected claims 15-17 and 19-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 19 are rejected as vague, indefinite and confusing in the recitation of “at least two therapeutically effective synergistic bacteriophage derived lytic enzymes” and “at least two bacteriophage derived synergistic lytic enzymes”, respectively, the Examiner alleging that it is unclear whether the “lytic enzymes” are derived by chemical, physical or biological means. In addition, the term “synergistic” is objected to, the Examiner remarking that it renders claims 15 and 19 confusing, vague, and indefinite since there is no clear indication of the amount, identity or source of the enzymes and for what purpose. Applicants respectfully traverse this rejection and submit that it is clear to the skilled artisan, including from a reading of the claims and the specification, and given their knowledge, what is meant by the claimed invention. Nevertheless, without acquiescing to the Examiner and without prejudice, Applicants have above amended claims 15 and 19, including to address the Examiner’s objections. In particular, claims 15 and 19 now recite “obtained from bacteriophage”, as suggested by the Examiner. Claims 15 and 19 further recite “wherein the combination of the at least two enzymes shows more than additive killing on a logarithmic scale”, which serves to clarify the synergistic nature of the bacteriophage derived lytic enzymes. Applicants submit that instant pending claims 15 and 19 are definite and particularly point out and distinctly claim the subject matter of the invention.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, second paragraph, may properly be withdrawn.

The 35 USC § 102 and § 103 Rejections

The Examiner has rejected claims 15, 16 and 19-22 under 35 U.S.C. 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischetti et al (U.S. Patent No. 6,264,945) in light of Marova et al (Folia Microbiol. 38(3):245-252 (1993)). Fischetti et al is cited as teaching a composition compressing at least two therapeutically effective lytic enzymes.

The Examiner points particularly to column 7, lines 9-25, of Fischetti et al as teaching that a phage lysin is combined with lysostaphin. Lysostaphin is noted as comprising hexosaminidase (N-acetylglucosaminidase), glycylglycine-endorpeptidase and N-acetylmuramyl-L-alanine-amidase, as demonstrated by Marova et al. The Examiner alleges that the claimed composition is anticipated by or alternatively, obvious from, the cited reference. In addition, claims 15-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischetti et al [I] (U.S. Patent No. 6,264,945) taken with Marova et al (Folia Microbiol 38(3):245-252 (1993)), Fischetti et al [II] (U.S. Patent No. 6,056,954), Sanz et al (Eur. J. Biochem. 187:409-416 (1990)) and Loeffler et al (Science 294:2170-2172 (2001)). Fischetti et al [II] is cited as strongly suggesting the use of several bacteriophage lytic enzymes in combination, the Examiner pointing particularly to column 13, lines 16-25. Loeffler et al is cited as teaching the favorable properties of the cell wall degrading enzyme Pal, while Sanz et al is cited as teaching the favorable properties of Cpl-1 lysozyme. The Examiner alleges that one would have been motivated in providing a combination of various bacteriophage derived enzymes for the expected benefit of a composition for controlling bacterial pathogens.

Applicants respectfully traverse the above 102 and/or 103 rejections and submit that claims 15-17 and 19-23, including as above amended, are not made obvious by the combination of any combination of Fischetti et al (I) and Marova et al and/or of Fischetti et al (I), Marova et al, Fischetti et al (II), Sanz et al and Loeffler et al. Applicants point out that claims 20 and 21 have been cancelled rendering the rejections of these claims moot. In addition, claims 15, 16, 19 and 22 have above been amended without prejudice. Applicants submit that claims 15-17, 19, 22, and 23, including as above amended, are not anticipated by or obvious in view of Fischetti et al (I) with Marova et al, or in view of the combination of Fischetti et al (I), Marova et al, Fischetti et al (II), Sanz et al and Loeffler et al. To anticipate a claim or to establish obviousness, a prior art reference, or the combination of references, must teach or suggest each and every element and limitation of the claim. Fischetti et al (I), alone, or in combination with Marova et al does not teach, nor does it suggest, each and every element of pending claims 15, 16, 19, 22 and 23, including as above amended. Further, the combination of Fischetti et al (I), Marova et al, Fischetti et al (II), Sanz et al and Loeffler et al does not teach or suggest each and every element

of pending claims 15-17, 19, 22, and 23. Applicants point out and underscore that, while the Examiner alleges that Fischetti et al (I) teaches that a phage lysin is combined with lysostaphin, anticipating the instant invention, in fact lysostaphin is not a phage enzyme. Also, Fishetti et al (I) teaches that lysostaphin is for treatment of *Staphylococcus aureus* bacteria, including at column 6, lines 50-57. The combination of Fischetti et al (I), Marova et al, Fischetti et al (II), Sanz et al and Loeffler et al does not teach or suggest the claimed compositions, and particularly do not teach or anticipate synergistic combinations or two or more bacteriophage lytic enzymes, particularly with activity against pneumococci as instantly claimed. None of the references alone, or in combination teaches or suggests the particular and specific claimed compositions and combinations of synergistic bacteriophage derived lytic enzymes, including for use as instantly claimed.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 102 and 103 rejections are obviated and request that they be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

KLAUBER & JACKSON, LLC

A handwritten signature in black ink, appearing to read 'Christine E. Dietzel', is written over a horizontal line.

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